5. 510(K) SUMMARY

Applicant: Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: 800-729-9010
Fax: 909-839-8804

Date: November 5, 2007

Contact Person: Natalie Bennington
Manager, Regulatory Affairs

Proprietary Device Name: CARTO® 3 EP Navigation System and Accessories

Common Device Name: Cardiac mapping system and surface reference device

Classification Name: Programmable diagnostic computer
(per 21 CFR 870.1245, Product Code DQK)

Predicate Device: CARTO® XP V7 EP Navigation System (K013083)
CARTO® RMT V8 EP Navigation System (K060047)
RefStar External Reference Patch (K982415, K061468)
EnSite System (K060954)

Manufacturing Facilities:

System & System Cables
Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel, 39120
Israel

Accessories (Accessory Cables)
Biosense Webster
15715 Arrow Hwy.
Irwindale, CA 91706

5.1 Substantially Equivalent To:

The Carto® 3 EP Navigation System is substantially equivalent to the CARTO® XP V7 EP Navigation System (K013083, cleared 11/21/01), the CARTO® RMT V8 EP Navigation System (K060047, cleared 6/19/06) and the RefStar External Reference Patch (K982415, cleared 8/10/98 and K061468, cleared 8/14/06), which are all manufactured by Biosense Webster. In addition, the CARTO® 3 System is also substantially equivalent to the EnSite System manufactured by Endocardial Solutions (K060954, cleared 4/21/06).

5.2 Description of the Device Subject to Premarket Notification:

The CARTO® 3 System is a new platform for the CARTO® Navigation System that incorporates new hardware and software updates.

The CARTO® 3 System is a catheter-based atrial and ventricular mapping system designed to acquire and analyze individual data points, and use this information to display 3D electroanatomical maps of the human heart in real-time. The location information needed to create the cardiac maps and the local electrograms are acquired using a specialized mapping catheter and reference device. The system allows real-time display of cardiac maps based on the received intra cardiac signals from the catheters in a number of different formats. For example, maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps and cardiac chamber geometry maps. The acquired patient signals; including body surface ECG and intracardiac electro grams may also be displayed on the display screen.

Unlike conventional mapping systems that utilize fluoroscopy to visualize the catheter, the CARTO® 3 System uses two distinct types of location technology. In order to locate the tip of the catheter, the System uses "Sensor Technology". In order to locate the electrodes on the catheter shaft, the System uses Active Current Localization (ACL) Technology. Six external reference patches (which are accessories to the system and needed for both tip and electrode localization) are placed externally on the patient's chest and back (three are placed on the chest and three are placed on the patient's back). Sensors at the distal end of each of the six "Patch Sensor Cables" attach to the external reference patches via a stud/snap connector.

When used with the CARTO® 3 System, the intracardiac location of the tip of the navigation catheter (such as the NaviStar Catheter) and the electrodes on the catheter shaft are referenced to the mean calculation obtained from the three sensors located in the Patch Sensor Cables (which are attached to the patient's back) and enable the CARTO® 3 System to construct 3D electrophysiological and electroanatomical maps of the human heart in real-time.

The new features offered with the CARTO® 3 System which differ from the current CARTO® XP V7 EP System include the following:

- Catheter shaft and electrode visualization.
- Ability to connect and visualize more than one catheter simultaneously.
- The CARTO® XP V7 System utilizes an external reference device that incorporates the reference sensor into the adhesive patches. This patch/sensor/cable device is a completely separate device and is sold separately from the CARTO® XP V7 System. The external reference for the CARTO® 3 System, on the other hand, is an integral component of the "Patch Unit" of the system. Only the adhesive patches are sold separately as accessories.

5.3 Indications for Use:

The CARTO® 3 EP Navigation System and accessories are intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of the catheter as well as display of cardiac maps in a number of different formats. For example, maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps and cardiac chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed on the System's display screen.

5.4 Performance Data:

The CARTO® 3 System and accessories underwent bench, animal and electrical safety testing. The CARTO® 3 System and accessories passed all intended criteria in accordance with appropriate test criteria and standards.

5.5 Overall Performance Conclusions:

Based on the results of the Risk Analysis, the bench, animal and electrical safety studies performed and the comprehensive safety analysis, we concluded that the risk to benefit ratio for the use of the CARTO® 3 System for catheter-based atrial and ventricular mapping has not been negatively affected by the proposed design changes. In summary, the CARTO® 3 System (which incorporates the external reference device within the system) described in this submission is substantially equivalent to Biosense Webster's CARTO® XP V7 EP System, the CARTO® RMT V8 EP System, the RefStar External Reference Patch and to Endocardial Solution's EnSite System and are as safe and effective as the predicate devices for catheter-based atrial and ventricular mapping.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

Biosense Webster, Inc.
c/o Ms. Natalie Bennington
Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K072202
Trade/Device Name: CARTO 3 EP Navigation System (Model FG-5400-00) and CARTO 3 External Reference Patches (Model: D-1283-01)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: November 5, 2007
Received: November 6, 2007

Dear Ms. Bennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K072202

Device Name: CARTO® 3 EP Navigation System and Accessories

Indications for Use:

The CARTO® 3 EP Navigation System and accessories are intended for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of the catheter as well as display of cardiac maps in a number of different formats. For example, maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, and cardiac chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed on the System's display screen.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Villeneuve

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072202